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DEPARTMENT OF HEALTH & HUMAN SERVICES

#4798

Public Health Service

NDA/IND

Food and Drug Administration
Rockville MD 20857

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TRANSMITTED VIA FACSIMILE

James H. Conover, Ph.D.
Executive Director
Drug Regulatory Affairs and Compliance
The Purdue Frederick Company
100 Connecticut Avenue
Norwalk, Connecticut 06850-3590

cc:
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RE: NDA#20-553
OxyContin (Oxycodone hydrochloride)
MACMIS ID #3673

Dear Dr. Conover:

This is in response to The Purdue Frederick Company's (PF) January 11, 1996, request for comments on revised launch materials for OxyContin. These materials include:

OxyContin Launch Visual Aid (version A4847)
OxyContin Journal Ad (version A4895)
OxyContin Wholesaler Sell Sheet (version A4916-WSS)
OxyContin Pharmacy Sell Sheet (version A4916-RSS)
OxyContin Titration Guidelines Card (version A4898)
OxyContin Conversion Calculator (version A4894)
OxyContin File Card (version A4893)

The Division of Drug Marketing, Advertising and Communications (DDMAC) has reviewed these materials and offers the comments that follow. Since many materials contain similar promotional concepts, DDMAC's comments on a specific claim or presentation should be applied to all similar claims or presentations throughout all current and future promotional materials.

Visual Aid and File Card

- **Fair Balance Statement (Pages 3)**
  ("OxyContin Tablets are to be taken whole....")

  The balancing statement is not presented with a prominence and readability comparable to the claims made. DDMAC suggests the presentation of this statement comply with regulations.

- **The logical next step for patients, with persistent pain, no longer responding to or tolerating nonopioids.**

  DDMAC understands that around-the-clock therapy is

preferable to prn therapy for some patients. However, DDMAC adheres to the position that Step 2 therapy includes opioids for mild-to-moderate pain. OxyContin is indicated for moderate-to-severe pain and, therefore, should not be presented as Step 2 therapy on the analgesic pain ladder. Thus, DDMAC suggests this presentation be revised, for example, to: "The logical next step for patients, with persistent pain, no longer responding to or tolerating nonopioids and opioids for mild-to-moderate pain."

- **Presentations that include the osteoarthritis trial**

  It would be misleading to imply that OxyContin is indicated for pain that is not moderate-to-severe. Thus, DDMAC suggests that presentations about this osteoarthritis trial include the patient population as described in the approved labeling: "...133 patients with moderate-to-severe osteoarthritis pain, who were judged as having inadequate pain control with prn opioids and maximal non-steroidal anti-inflammatory therapy."

- **In this study, OxyContin 20 mg q 12...**
  -Significantly decreased pain
  -Improved quality of life, mood and sleep

  This claim would be misleading because it fails to disclose that these improvements were in comparison to placebo only. Therefore, DDMAC suggests this claim be revised to include the qualifying statement "relative to placebo" as consistent with the approved labeling.

Journal Ad

Comments on the claims in the visual aid should be applied to the journal ad.

Pharmacy Sell Sheet

DDMAC notes that the statement "Warning - May be habit forming" was enlarged on the wholesaler sheet, but not on the pharmacy sell sheet. DDMAC suggests this be statement also be enlarged on the pharmacy sell sheet to increase its prominence.

If PF has any questions or comments, please contact the undersigned by facsimile (301) 594-6771 or by written communication at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, 5600 Fishers Lane, HFD-40, Room 17B-20, Rockville, MD 20857.

In all future correspondence regarding this matter, please refer to MACMIS ID #3673, in addition to the NDA number.

Sincerely,

Diane Shnitzler

Diane Shnitzler
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications